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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,624	PAXSON ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 45-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 11/19/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 11/19/2008, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-22 and 45-48 are the current claims hereby under examination.

Claim Rejections - 35 USC § 101

Response to Arguments

Applicant's arguments, filed 11/19/1008, with respect to the rejection of claims under 35 USC 101 have been fully considered and are persuasive. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112-first paragraph

Response to Arguments

Applicant's arguments, filed 11/19/1008, with respect to the rejection of claims under 35 USC 112 first have been fully considered and are persuasive. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112-second paragraph

Response to Arguments

Applicant's arguments, filed 11/19/1008, with respect to the rejection of claims under 35 USC 112 second have been fully considered and are persuasive. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 102-Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-22 and 45-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Sauro et al. (2003).

Sauro et al show a system, computer-implemented method, and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface (GUI) to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior (figure 11). In figure 11 and figure 12 of Sauro et al, the elements of modeling component having a GUI providing means for accepting user input via a tool palette to generate a block diagram of a plurality of related chemical reactions that make a biological system. The figure also depicts an analysis environment displaying the dynamic behavior of the biological system, and a simulation engine. Sauro et al show that the dynamic behavior of the system is modeled using a

stochastic computational model (p 355 and 364). Sauro et al. discloses the capabilities of simulating the dynamic behavior along with the ease of annotating and editing within the JDesigner environment. Moreover, Sauro teaches at page 364 that Jarnac enables modifying, through the SBW interface, the parameters and initial conditions, i.e. annotating the graphical model in response to a user requesting to add annotations to the model that are provided by the user. In addition, Sauro teaches that JDesigner also has annotating capabilities to support layout information upon request by a user. Furthermore, the JDesigner environment works well with the Jarnac environment to build an easy to use systems biology development environment. With regards to applicant's newly added means plus functional language in claim 45, Suaro teaches at page 365, first two lines, that the Jarnac application has the means for generating dynamic behavior of the modeled biological system, which actually carries out the simulation.

Response to Arguments

Applicant's arguments filed 11/19/2008 have been fully considered but they are not persuasive.

With respect to claim 1, applicant argues that Sauro does not teach generate as output dynamic behavior of the biological system using a first type of computational model for the first chemical reaction, a second type of computational module for the second chemical reaction, and the specified constraint. Applicant further argues that being able to run multiple models "simulataneously" is not equivalent to running a single model that includes a first chemical reaction and a second chemical reaction, wherein

each reaction is modeled using different computational models. In addition, Applicant states that Sauro discloses that Jarnac can only simulate models that have one computational type.

Applicant's arguments are not found persuasive as being able to run different models simultaneously, wherein each model comprises a reaction scheme using a set of equations for simulating said reaction, reads on a model, comprised of multiple models running simultaneously, wherein the different reactions comprising the different models reads on different computational models representing the different reactions. Furthermore, Sauro at page 357 that the capabilities of the SBW is enabling one module to invoke a service method in another module and that a module can run whatever services are requested, i.e. simulations. Moreover, Sauro at pages 361-362exemplifies one module to be run in the SBW environment which comprises two classes, one class comprised of trigonometric functions and another that provides logarithmic functions. This is a very simple example described by Sauro that describes a single model running two different computational modules at the same time. Sauro describe throughout the paper that reactions are simulated by equations. The Jarnac environment enables a module to be comprised of different classes wherein each class may comprise a different reaction module, all of which can be run through the SBW environment simultaneously. Sauro describes the SBW environment as supporting languages such as java, which is an object orientated language, wherein each reaction can be modeled by creating a different class and run simultaneously within one module as exemplified at pages 361-362.

In addition, applicant's arguments are not found persuasive because Sauro at page 364 teaches JDesigner, where a model describing chemical reactions is entered along with rate laws. JDesigner then stores each of the created models, which each comprises representations of chemical reactions. Sauro at page 364, teaches Jarnac, which loads each of the models and can modify constraining parameters, simulation times, and initial conditions and run each of the models simultaneously through the SBW interface. In addition, Sauro at page 354, second paragraph describe the GUI based simulator wherein models in the form of networks are drawn on a canvas and the diagrams converted into a mathematical representation for simulation. In addition, Sauor at page 363, first paragraph dscribe the BioSPICE/SBW bridge which enables developers of BioSPICE to implement a data flow GUI that allows users to direct data from one module to another, which allows users to chain a series of processes in whatever fashion suits their needs. Sauro at page 364, third paragraph describe the capabilities of Jarnac, which supports multiple simulation instances, where more than one simulation can be active at any one time, all of which reads on executing one of the first chemical reactions and the second chemical reaction identified by a first reaction, the first chemical reaction being executed using a first type of computational model concurrently with the second chemical reaction being executed using a second type of computational model.

Applicant’s arguments are not found persuasive as Sauro does not disclose anywhere that Jarnac can only simulate models that have one computational type.

Applicant presents similar arguments with respect to claims 9, 16, and 45, which have been addressed above with respect to claim 1. Therefore, applicant's arguments with respect to claims 9, 16, and 45 are not found persuasive for the same reasoning as presented above in the instant office action.

Maintained:

Claims 1-5, 8-11, 14-17, 20-22, 45, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Hucka et al. (Pacific Symposium on Biocomputing Vol. 7, p.450-461, 2002).

The claims are directed to a system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior.

Hucka et al. show a system, computer-implemented method, and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior (figures 1 and 2). Hucka et al. describe Jdesigner, a software providing a GUI to accept user commands and data (sect. 5.2). Jdesigner

provides a tool palette aiding in the construction of the of a block diagram model, as is seen in figure 1 (figure 1 and p. 452). As shown in figure 1, the modeling component includes a block diagram of related chemical reactions. Hucka et al. show that the simulation engine, generates the dynamic behavior of the system using a stochastic computational model (p. 459, sect 5.8-9). Huck et al. also teaches at page 450, several programs for generating the dynamic behavior, such as Jarnac and Virtual Cell, which reads on the means plus functional language of amended claim 45.

Response to Arguments

Applicant's arguments filed 11/19/2008 have been fully considered but they are not persuasive.

With respect to claim 1, applicant argues that Hucka does not teach generate as output dynamic behavior of the biological system using a first type of computational model for the first chemical reaction, a second type of computational module for the second chemical reaction, and the specified constraint. Applicant further argues that being able to run multiple models “simulataneously” is not equivalent to running a single model that includes a first chemical reaction and a second chemical reaction, wherein each reaction is modeled using different computational models. In addition, Applicant states that Hucka discloses that Jarnac can only simulate models that have one computational type. Applicant further argues that the Gillespie and Gibson simulators support stochastic models, whereas the Jarnac simulator supports ODE-based models, wherein it is not dislosed a system that uses multiple simulators that simulate different computational model types to execute a single model.

Applicant's arguments are not found persuasive as Hucka teach at page 450 that SBW has enabled interoperability between a set of tools, such as BioSpice and Jarnac. Huck at page 451 describes the support ability for Java, which is not limited to one type of computational modeling. Huck further describes at page 451, last paragraph that the flow of control is entirely determine by what the individual modules and the users do, such as enabling access to all modules in the SBW environment in a single application. For example, within one module using JDesigner and Jarnac to run a simulation, the user can create the type of desired module, which can be comprised of different classes each class modeling a different chemical reaction as is inherent in the Java programming capabilities. The SBW environment can enable the interaction of the different tools and enables GUI control over running the module and its services at the same time.

In addition, Hucka et al. at section 5.7 teach a graphical user interface that enables users to set up simulation runs, edit parameters, or variables, i.e. constraints for the chemical reactions, and plot the resulting run. The graphical user interface is a graphical model of the imported JDesigner models, which comprise chemical reactions as taught in section 5.2. The JDesigner model stores each of the created models, which may comprise one or more chemical reactions. Furthermore, the interface, which runs similarly to Jarnac, can load the one or more models and run them. Furthermore, Hucka et al. at section 5.6 teaches MATLAB model generator, which enables analysis of the models created in JDesigner, i.e. create the ordinary differential equations used

to simulate the chemical reactions, which comprise each of the models, which reads on applicant's arguments.

Hucka et al. at section 5.7 teach a graphical user interface that enables users to set up simulation runs, edit parameters, or variables, i.e. constraints for the chemical reactions, and plot the resulting run, i.e. generate as output dynamic behavior of the biological system. Furthermore, the user interface working analogously to Jarnac, may run the one or more loaded models created in JDesigner, wherein the models each may comprise one or more chemical reactions along with edited parameters or variables, i.e. constraints for each of the chemical reactions, which reads on point 2) of applicant's arguments.

Applicant presents similar arguments with respect to claims 9, 16, and 45, which have been addressed above with respect to claim 1. Therefore, applicant's arguments with respect to claims 9, 16, and 45 are not found persuasive for the same reasoning as presented above in the instant office action.

Double Patenting-Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 and 45-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19, 26 and 64 of copending Application No. 10/783,628. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant case the claims are drawn system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

In comparison the claims of copending Application No. 10/783,628 are drawn system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an

analysis environment to display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-22 and 45-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19, 32, and 38-39 of copending Application No. 10/783,552. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant case the claims are drawn to a system, computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

In comparison the claims of copending Application No. 10/783,552, are directed to a system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic

behavior for the biologic system; and an analysis environment to display the dynamic behavior.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments:

Applicant has stated they will submit a terminal disclaimer if the instant claims are deemed allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin/

Primary Examiner, Art Unit 1631